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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/526,855	03/17/2000	Hyun K. Kim	15280W003000	3023

20350 7590 09/24/2003

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EXAMINER
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BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/24/2003

29

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/526,855

Applicant(s)

KIM ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-65 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-11, 18, 24, 25, 36-38, 44, 46, 49, 61 and 63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**First Office Action on the Merits of a RCE**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Status of the Claims***

2. Claims 1-15 and 17-65 are pending in the present application. Claims 4, 12-15, 17, 19-23, 26-35, 39-43, 45, 47, 48, 50-60, 62, 64 and 65 stand withdrawn from further consideration as being drawn to a nonelected invention. Claims 1-3, 5-11, 18, 24, 25, 36-38, 44, 46, 49, 61 and 63 will be examined to the extent they read on the elected species and have been extended to include compounds of formula I wherein R<sup>1</sup> is N(CH<sub>3</sub>)<sub>2</sub>; R<sup>2</sup> is hydrogen or alkoxy and R<sup>3</sup> is alkoxy or acyloxy.

***Double Patenting***

3. The provisional rejection of claims 1-3, 5-8, 24, 25 and 49 under the judicially created doctrine of obviousness-type double patenting over claims 1-26 of copending Application No. 09/ 180,132 is maintained and claims 9, 36-38, 46, 61 and 63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-26 of copending Application No. 09/180,132.

Applicant has stated on the record that the appropriate Terminal Disclaimer will be filed upon finding of allowable subject matter.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3, 5 and 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "if R<sup>1</sup> is -N(CH<sub>3</sub>)<sub>2</sub>, R<sup>2</sup> is hydroxyl, R<sup>4</sup> is alkyl and X is =O, then **R<sup>3</sup> is other than hydroxyl**" in lines 19 and 20. There is insufficient antecedent basis for this limitation in the claim. The definition of R<sup>3</sup> does not include hydroxyl and, thus, there is no antecedent basis for this proviso. It is suggested that said proviso be deleted from claim 1.

***Claim Rejections - 35 USC § 102***

6. The rejection of claims 1-3, 6-8 and 49 under 35 USC 102(b) over Cook et al. ('548) is withdrawn.

***Claim Rejections - 35 USC § 103***

7. Claims 1-3, 6-11 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. ('548).

Cook et al. teach a genus of 17 $\beta$ -acetyl substituted compounds (see the entire article, especially col. 3, line 45 - col. 4, line 43; col. 20, Table 2, compound #8a). The

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reference teaches the compounds have anti-progestational and/or antiglucocorticoid properties (see col. 2, lines 26-28; col. 7, lines 3-42).

The instant claims differ from the reference by reciting compounds not exemplified. For example, the instant claims encompass compounds wherein X as defined by the present invention is  $=N-OR^5$  and/or  $R^3$  is acyloxy other than acetyloxy. However, Cook teaches X is O or  $NOCH_3$  and  $R^1$  (i.e.,  $R^3$  as defined by the instant invention) can be  $OC(O)CH_3$  or  $OC(O)R^5$  where in  $R^5$  is saturated or unsaturated  $C_{2-8}$  alkyl (see col. 2, lines 49-54). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to make any of the species of the genus taught by the reference, for example, the compounds exemplified by the reference wherein X is  $NOCH_3$  or wherein  $R^1$  (i.e.,  $R^3$  as defined by the instant invention) is  $OC(O)R^5$ , with the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole. The motivation would be based on the desire to obtain additional compounds having anti-progestational and/or antiglucocorticoid properties for use as taught by Cook et al.

8. Claims 1-3, 5-11, 18, 24, 25, 44, 46, 61 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. ('548) and Peeters ('787) in combination.

Cook et al. teach a genus of  $17\beta$ -acetyl substituted compounds (see the entire article, especially col. 3, line 45 - col. 4, line 43; col. 20, Table 2, compound #8a). The

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reference teaches the compounds have anti-progestational and/or antiglucocorticoid properties (see col. 2, lines 26-28; col. 7, lines 3-42).

Peeters et al. teach a generic group of steroids that encompass the compounds taught by Cook having antiglucocorticoid property useful for treatment of anxiety disorders (see the entire article, especially col. 1, line 54 – col. 2, line 43). Peeters teach the 17 $\beta$ -position can contain a substituted or unsubstituted C1-C6 acyl group. Peeters teach substituents such as hydroxyl, alkoxy and acyloxy (see col. 2, lines 35-38).

Based on the combined teachings of the above cited references, it would have been obvious to make the compounds as exemplified by Cook wherein the 17 $\beta$ -acetyl group is substituted with hydroxyl, alkoxy or acyloxy with the reasonable expectation that said compounds would have antiglucocorticoid property as taught by Peeters. The motivation would be based on the desire to make antiglucocorticoid steroids for use in treatment of anxiety and other disorders as taught as taught by prior art.

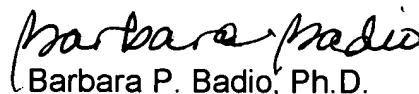
### ***Telephone Inquiry***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308- 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in cursive script, reading "Barbara P. Badio".

Barbara P. Badio, Ph.D.

Primary Examiner

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BB

September 22, 2003